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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,211	01/30/2002	Klaus Schumann	3868-0103P	9968

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/31/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,211

Applicant(s)

SCHUMANN ET AL.

Examiner

Isis Ghali

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s) _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment B, filed 08/21/2003.

Regarding the applicants concern about not receiving a Notice of Draftsperson's Patent Drawing Review Form PTO 948, now, the Office of Initial Patent Examination (OIPE) are reviewing drawings in new utility and plant applications filed on or after November 29, 2000 and will not release applications to the Technology Centers unless acceptable drawings are present. Drawings filed after the application has been released by OIPE are no longer required to be reviewed by the draftsman. The drawings will be accepted as publishable unless the Examiner is not able to use the new drawings in the examination of the application. The drawing filed with the present application is accepted by the examiner.

Claims 1-5 have been canceled, and claims 6-10 have been added per applicants' amendment B, Paper No. 12. Claims 6-10 are included in the prosecution.

(a) Claim Rejections - 35 USC § 103:

The Standing Rejection:

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/34633 ('633) in view of US 5,626,866 ('866).

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WO '633 teaches a dressing set (substrate sections) that keeps the active agent in a reservoir at a constant level for a prolonged storage time (abstract; page 2, last paragraph). The dressing set comprising a backing; a reservoir containing at least one pharmaceutically active substance; a pressure sensitive adhesive surface layer on one of the surfaces of the backing layer (reads on one of the surfaces of the substrate sections rendered pressure sensitive adhesive); and more than one peel stripes, i.e. the carrier sections (abstract). The peel stripes extend beyond the edges of the dressing and are overlapping (page 4, paragraph 3, figure 2). It is evident from figure 2 that both carrier layer sections are overlapping in the center of the dressing (claim 4). Figure 2 also shows that one carrier section is wider than the other by the amount of the overlap (claim 2). It is also expected that if we have a carrier layer and divide it into two pieces and partially overlap the two pieces on top of each other, it is expected to have shorter width of the overlapped sections than the undivided carrier. Thus, in order to have the overlapped carrier sections having same width of the undivided carrier layer we have to increase the width by the amount of the overlap and this increase can be added on one side or divided on both sections of the carrier, and in the later situation it will give half the amount of overlap on each side (claim 3). In any events, applicants are not claiming any dimensions of the carrier layer sections or the overlapping portions that impart patentability to the claims.

However, WO '633 does not teach that the substrate sections are sealed in a bag.

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US '866 teaches a transdermal drug delivery device or patch to deliver volatile drugs comprising a drug-containing adhesive layer or reservoir and a peelable release liner (abstract; col.1, lines 10-12; col.3, lines 48-49; col.8, lines 35-37). The release liner formed of two stripes that overlap in the center (col.12, lines 17-23; figure 4). The patch is sealed in a pouch (col.12, lines 32-33). The adhesive used in the device is a pressure sensitive adhesive (col.8, lines 30-37).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of WO '633 that teaches dressing or patch comprising active agent and release liner comprising two overlapping sections with the teachings of US '866 that sealed the patch containing volatile drugs in a bag or pouch, to obtain a patch with overlapped release liner-sections sealed in a bag, motivated by the desire of WO '633 to keep the active agent in the reservoir at a constant level for a prolonged storage time, or motivated by the desire of US '866 to protect volatile drugs during storage (as also desired by applicants), with reasonable expectation to achieve increased stability of the drugs in the patch and prevent their leak from the reservoir layer during storage of the patch in a sealed bag.

Applicants' Arguments:

Applicants traverse the above rejection by arguing that WO '633 and US '866 concern the loss of the active substance rather than avoidance of leakage of the pressure sensitive adhesive (PSA). WO '633 teaches a dressing comprising non-occlusive backing that has one adhesive side, a reservoir which comprises active

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agents, but neither rendered pressure sensitive adhesive nor made on the basis of PSA. The backing layer projects beyond the reservoir such that it forms adhesive edge.

US '866 does not teach the formation of carrier layer sections which overlap each other, nor the leaking of the PSA is disclosed or suggested.

Applicants further argue that the combination of WO '633 and US '866 fails to make the present invention obvious to the skilled artisan because these references fail to disclose any information leading towards the problem of leaking of the PSA.

Response to Arguments:

The above applicants' arguments have been fully considered but they are not persuasive. The present claims are directed to an article, and all the elements of the article are disclosed by the WO '633 in view of US '866 and the intended use of the article as to protect against the leakage of the PSA does not impart patentability to product claims. Applicants admit that the structure of the dressing disclosed by WO '633 is the same as the structure claimed by applicant except for the reservoir is not made of PSA. However, the reference disclosed a PSA layer on the reservoir layer, and that is exactly how applicants rendered the matrix PSA as per present disclosure at page 3, forth paragraph. The claim recites either the matrix is made of PSA or rendered PSA. Further, it is expected for the dressing of WO '633 that has the same structure of overlapping carrier and reservoir rendered adhesive to perform the same function as desired by applicants, i.e. avoidance of the leakage of the PSA.

Regarding US '866, the reference is relied upon for the solely teaching of the packaging of the patch, which is well known in transdermal art. US '866 further teaches that the patch has overlapping sections of the carrier layer and PSA contacting the skin, i.e. to render the reservoir adhesive (Figure 4; col.8, lines 35-37).

In response to applicant's argument that the combination of the references would not lead to the present invention, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, motivation would arise from the skill in the art to package the patch to protect the constituents, either from leaking or from the environment.

(b) Claim Rejections - 35 USC § 103:

The Standing Rejection:

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,174,399 ('399).

US '399 teaches a method of producing an adhesive bandages comprising a backing layer, on its center deposited a pad (represents the substrate section) and covered by overlapping release layers (carrier sections) that extends beyond the pad (col.2, lines 10-15; col.3, lines 40-43; figure 1). The process of making the adhesive

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bandage comprises the steps of laminating the adhesive bandages then applying the release layers that fed from two rolls and overlap in the center of the pad (col.3, lines 38-42; Figure 1).

The reference differs from the present invention in that it does not teach the carrier layer sections (release liners) are applied after the sections have been overlapped. However, the reference teaches, as also evident from Figure 1, that both sections of the liner are overlapped during the process of their application because they are fed from two rolls.

The process comprising the step of overlapping the release liner before application of the substrate does not impart patentable distinction to the process of the prior art that overlapped the two portions during their application, nor resulted in a materially different product, absent evident to the contrary. Selection of any order of performing process steps is *prima facie* obvious in absence of new or unexpected results, see *In re Burham*, 154 F.2d 690 USPQ 330 (CCPA 1946); and *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce a substrate sections (patch) comprising a carrier layer sections that extend beyond the substrate sections and form a region of overlap, said process comprising the step of overlapping the carrier layer sections before or during application to the substrate sections because the change of sequence of the step is within the skill in the art as it does not materially affect the end product, with reasonable

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expectation of the delivered substrate as a stable drug delivery device or wound dressing.

Applicants' Arguments:

The claimed process is distinct from the process of US '399 in that the two carrier layer sections are first overlapped then the substrate layer is supplied. The process of US '399 disclosed the laminate is cut after assembly into strips. US '399 fails to teach the dispensing process.

Response to Arguments:

The above applicants' arguments have been fully considered but they are not persuasive. It is evident from Figure 1 of the reference that both sections of the liner are overlapped during the process of their application because they are fed from two rolls. The process comprising the step of overlapping the release liner before application of the substrate does not impart patentable distinction to the process of the prior art that overlapped the two portions during their application, nor resulted in a materially different product, absent evident to the contrary. Selection of any order of performing process steps is *prima facie* obvious in absence of new or unexpected results, see *In re Burham*, 154 F.2d 690 USPQ 330 (CCPA 1946); and *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

(i.e., cutting the laminate) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to “dispensing” process, the word “to dispense” means “to administer”, and that what the reference disclosed. The reference teaches “application of the release paper to the laminate to overlap along the center”, and “to apply” means “to put on”. Applicants fail to show criticality in the dispensing process or how it is different from the application process disclosed by the reference and how is the patch that have PSA dispensed to the carrier is superior to one that is applied to the carrier.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600